



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,189	11/13/2003	Lilip Lau	PARCR 65988	9393
7590 08/22/2005			EXAMINER	
Fulwider Patton Lee & Utecht, LLP			GILBERT, SAMUEL G	
Tenth Floor			ART UNIT	
6060 Center Drive			PAPER NUMBER	
Los Angeles, CA 90045			3736	

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TW

Office Action Summary	Application No.	Applicant(s)	
	10/714,189	LAU ET AL.	
	Examiner	Art Unit	
	Samuel G. Gilbert	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/12/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 – claim 60 sets forth a pressure of 3-4 mmHg inherently as set forth on page 7 of the applicant's arguments filed 6/2/2005. Therefore claim 66 sets forth a range outside the range set forth in claim 1.

Claim Objections

Claim 61 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 60 sets forth a pressure of 3-4 mmHg inherently as set forth on page 7 of the applicant's arguments filed 6/2/2005, therefore claim 61 does not further limit claim 60.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al (5,150,706).

Claim 54 – net –12- is an elastic cardiac harness, therefore inherently self sizing, column 5 lines 52 and 53. Net –12- would have a different compliance for different size hearts and different size elements. Therefore the examiner is taking the compliance as claimed as an inherent feature of Cox et al, when a certain size net –12- is put on a certain size heart. Further, the compliance is directed to an intended use and method of using the device. If the claimed invention was on a shelf with net –12- of Cox et al the devices could be identical. The net –12- is sized to cover at least a portion of the heart. Further, the net –12- is compressible, and therefore capable of being implanted minimally invasively. The term minimally invasively has not been limited by a specific definition in the specification and is therefore being taken as a relatively broad term.

Claim 55 – is directed to an intended use of the harness and it is the examiner's position that the harness, net –12-, of Cox et al would be capable of generating the claimed compression force.

Claim 56 – the net –12- is made from an elastic material, column 5 lines 52/53.

An elastic net would inherently have a deformed shape and recovered shape.

Claims 57-59 – the net -12- is capable of being compressed and delivered as claimed.

Claims 60 and 61 - the net –12- would have a net pattern for applying a compressive force. The compliance is capable of being expressed in terms of the pressure the harness applies to the heart. The range of compliance is a function of the heart size and the size of the net. The selection of a particular net for use on a particular heart would provide the claimed compliance. Therefore the net –12- is capable of providing the claimed compliance.

Claim 62 – the net -12- is capable of being compressed and delivered as claimed.

Claims 63-66 – the claims are replete with functional language, the device of Cox et al. teaches a net –12- that is capable of performing.

Claims 54-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Alferness (5,702,343).

Claim 54 - Alferness teaches a heart jacket formed of an elastic material, column 3 line 10. An elastic heart jacket, figures 3-5, is inherently self-sizing over the elastic range of the jacket.

Claim 55 – is directed to an intended use of the harness and it is the examiner's position that the jacket would be capable of generating the claimed compression source.

Claim 56 – the jacket is made from an elastic material, column 3 line 10. An elastic net would inherently have a deformed shape and recovered shape.

Claims 57-59 – the jacket is capable of being compressed and delivered as claimed.

Claims 60 and 61 - the net –12- would have pattern for applying a compressive force. The compliance is capable of being expressed in terms of the pressure the harness applies to the heart. The range of compliance is a function of the heart size and the size of the jacket. The selection of a particular jacket for use on a particular heart would provide the claimed compliance. Therefore the jacket is capable of providing the claimed compliance.

Claim 62 – the jacket is capable of being compressed and delivered as claimed.

Claims 63-66 – the claims are replete with functional language that the device of Alferness is capable of performing.

Response to Arguments

Applicant's arguments filed 6/2/2005 have been fully considered but they are not persuasive.

On page 8 of the amendment of 6/2/2005, the applicant argues that Cox et al does not disclose a cardiac harness capable of being applied about the heart minimally

invasively. It is the examiner's position that the only structure property set forth to limit the recited function is that the harness is compressible. Figures 1 and 2 of Cox et al. show the device in a compressed state. Further, the term minimally invasively has not been limited by a specific definition in the specification and is therefore being taken as a relatively broad term.

The applicant further argues that Cox et al is placed on a non-beating heart therefore compliance and self-sizing are non-factors. The actual use of Cox does not limit what the device of Cox et al is capable of doing. It is the examiner's position that the device is capable of performing the recited function as claimed even though it would be performed in a method not set forth in Cox et al. The applicant has not claimed the method of using the cardiac harness only the cardiac harness itself, therefore the recited prior art need only to be capable of performing the function and not actually teach the method.

The applicant further argues that Cox et al. does not teach a device that is "implanted". The claim language in question here is "the cardiac harness being compressible to be implanted about the heart minimally invasively". It is unclear exactly what structural limitation of the applicant's device provide the ability to be "implanted" other than the recited compressibility. The standard definition for "implant" includes "to insert in a living site", "Webster's Ninth New Collegiate Dictionary, number 2. The device of Cox et al. is clearly capable of being inserted into the body of a living person.

Now, regarding the rejections based on Alferness set forth on page 9, the applicant argues that the device of Alferness is not "self sizing". The applicant points out that the device requires a manual step to tighten the device. Further the applicant argues that the device is not self sizing while it is on the heart because the device is only an "expansion constraint". The applicant argues that the device fitted to a predetermined size and must be adjusted for size reduction as the cardiac size is reduced, and further that the proximity of the opposing lateral edges are manually adjusted.

Regarding the above, it is the examiner's position that the applicant has selected portions from a plurality of embodiments of Alferness and combined them as one argument the selected points/embodiments were not relied on by the examiner in forming the rejection. It is the examiner's position that the device is self sizing over at least the elastic range of the jacket. Column 3 lines 21-26, sets forth at least some expansion of the elastic material and further, elastic material inherently contracts. Therefore the examiner believes the device of Alferness is self sizing. The applicant has not set forth any specific structure to perform the function of self sizing therefore self sizing over even a limited range meets the language of the claim.

Further, the applicant seems to be arguing that their device does not have any expansion limit. The applicant's device is a mechanical band that can only expand a finite amount. The particular amounts have not been set forth in the specification or claims. If a band having a maximum expanded circumference is used on a heart that

wants to expand to a larger size than that of the band the band will not have a compliance as claimed or the band will break. From a different point of view, one of the applicant's bands applied to an infant heart will not have the claimed compliance if applied to a normal sized adult heart. Therefore the size of the band and the size of the heart.

Finally, even if the sleeve of Alferness is manually adjusted to be placed on the heart and manually adjusted after the heart remodels for at least the time period where the jacket is placed on the heart and before it remodels the jacket formed from an elastic material will be self sizing during cardiac filling, column 3 lines 25 and 26.

With regard to the applicant's arguments set forth on page 10, the applicant argues that neither Cox nor Alferness disclose a device having a compliance of 3-4 mmHg. The examiner agrees that neither Cox nor Alferness sets forth a compliance in the range as claimed. However, the applicant has claimed "compliance expressed in terms of the pressure the harness applies to the heart" and with the selection of a certain size harness as set forth in Cox or Alferness placed on a particular sized heart will inherently produce a compliance as claimed.

Also on page 10 the applicant argues that structural configuration, pattern of the harness and the materials of the harness will have an effect on the compliance of the device as well as the size of the harness and the heart. The examiner does not disagree that that structural configuration, pattern of the harness and the materials of

the harness will have an effect on the compliance however, the applicant has not set forth any of the specific materials, patterns or configurations that would have any effect on the compliance of the harness when the compliance is expressed in terms of the pressure the harness applies on the heart. It is the examiner's position that no matter what the material, pattern, or configuration of the harness there is at least one sized heart that will produce a pressure of 3-4 mm Hg to the harness. If a harness has a circumferential minimum size of 12 inches and a heart has a maximum circumferential size of 11 inches what will the compliance expressed in terms of the pressure the harness applies to the heart be? It is the examiner's position that the compliance will be zero because such a sized heart will not apply any pressure to harness.

If a harness has a circumferential minimum size of 11 inches and a heart has a maximum circumferential size of 12 inches what will the compliance expressed in terms of the pressure the harness applies to the heart be? The examiner does not believe this pressure will be between 3-4 mm Hg.

Conclusion

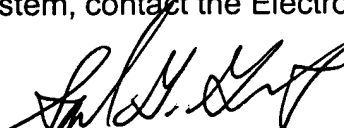
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Samuel G. Gilbert
Primary Examiner
Art Unit 3736